UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,712	11/08/2005	Marc Eloit	270423US0XPCT	9314

22850 7590 11/16/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/530,712	ELOIT ET AL.	
	Examiner	Art Unit	
	Michael Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-31 and 36-63* is/are pending in the application.

4a) Of the above claim(s) *25, 30, 36-51, 56-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24, 26-29, 31, 52-55 and 61-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 24, and 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 24 recite the limitation "the unmodified replicating adenovirus" in lines 2-3 and 3, respectively. There is insufficient antecedent basis for this limitation in the claims.

Claims 52-54 recite the limitation "the original replicating adenovirus" in lines 6 and 8 of claim 52, and in lines 2-3 of claims 53 and 54. There is insufficient antecedent basis for this limitation in the claims. This rejection affects all dependent claims.

Claim 52 recites, in part (b), that the nucleic acid molecule comprises between 10 and 1,000 bp of the original adenovirus located upstream of the deleted portion. By the language of claim 22 (from which claim 52 is dependent), the adenovirus only comprises a maximum of 310

bp "upstream" of the deleted portion. It is thus unclear what the remaining nucleic acid sequence (e.g. the remaining ~ 700 bp) might be.

Claim Objections

Claims 52 and 54 are objected to because of the following informalities: the terms "between 10 and 1,000 bp", "between 10 and 5,000 bp" and "between 10 and 1,000 bp" should be "between 10 to 1,000 bp", "between 10 to 5,000 bp", etc.. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22, 26-29, 31, and 52-55 are rejected under 35 U.S.C. 102(b) as being taught by Soudais et al (2001, of record).

Soudais et al teaches the generation of recombinant canine type 2 adenoviruses (see abstract) with deletions in the region that corresponds to residues 1-410 of SEQ ID NO: 12 (Fig. 1). Specifically, Soudais et al teach a series of deletion mutants in which the GFP gene is inserted via homologous recombination into the E1A promoter and coding region. A portion of the genome from base pair 356 to the E2 region at base pair 2145 (see figure 2) by inserting a heterologous GFP cassette and then inserting a loxP sites at base pairs 173 and 2081 (figure 2b, and page 635 second column last paragraph –636 first column). Soudais teaches the particular

vector CAVGFP-4Δ5, which specifically has the base pairs 302-356 deleted from the CAV-2 genome, thus the vector comprises the deletion of pairs 311-319, and has the GFP cassette inserted in this region (see figure 2). Soudais et al teach the generation of infectious virus that can replicate using these constructs (figure 5). Soudais et al purify the viral vectors by CsCl centrifugation and resuspension in PBS, considered a "pharmaceutical composition" absent a limiting definition in the specification. The CAV-2 vectors of Soudais et al comprised at least the upstream 302 bp, or at least 10 to 1,000 bp downstream of CAV-2 (Fig. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soudais et al (2001, of record) in view of Haddada et al (U.S. patent 6,294,377, 2001).

The teachings of Soudais et al are as above and applied as before. In addition, Soudais et al teach the advantages of their CAV-2 vectors in a clinical setting (page 639, ¶ linking first and second columns). Soudais et al do not teach a step of administering their vectors.

Haddada et al teach the use of CAV-2 vectors expressing heterologous genes in order to induce an immune response in humans, which, absent evidence to the contrary, includes inducing antibodies. See in particular col. 2, lines 44-61, col. 3, lines 24-38, col. 4, lines 11-20, and col. 5, lines 11-16.

The claimed methods are essentially disclosed by Haddada et al with the exception of using CAV-2 vectors comprising the claimed deletion. The ordinary skilled artisan, seeking a method to induce an immune response to a given antigen in a patient (such as a human) using an adenoviral vector, would have been motivated to use CAV-2 deletion vectors of Soudais et al with the methods of Haddada et al because Soudais et al teaches the deletion mutants to be useful and advantageous for this clinical applications (such as administration to humans). It would have been obvious for the skilled artisan to do this because of the known benefit of generating an immune response to a given antigen by administration of CAV-2 vectors as taught by Haddada et

al. Given the teachings of the cited references and the level of skill of the ordinary skilled artisan at the time of applicants' invention, it must be considered, absent evidence to the contrary, that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633